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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,218	01/20/2004	Durward I. Faries JR.	1322.0057CNT	6438
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EDEL, SHAPIRO & FINNAN, LLC 1901 RESEARCH BOULEVARD SUITE 400 ROCKVILLE, MD 20850			EXAMINER JAGAN, MIRELLYS	
			ART UNIT 2859	PAPER NUMBER

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,218

Applicant(s)

FARIES ET AL.

Examiner

Mirellys Jagan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/1/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 2/10/05, disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent 6,722,782 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 71 and 72 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent 5,875,282 to Jordan et al [hereinafter Jordan].

Jordan discloses a medical device (10) for a medical item (16), the device comprising:
a base (housing 10) and at least first (88) and second (90) panels attached to the base;
a receptacle (12) defined between the panels for receiving the medical item (16), wherein the medical item has a particular temperature range for utilization; and
a temperature sensor assembly (80, 82, 84, 86) to directly measure the temperature of the medical item (16) and provide a visual indication of the measured item temperature;

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wherein the temperature sensor assembly is affixed to the first panel (88) (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Furthermore, the method steps of claim 72 will naturally be followed during the operation of the device disclosed above by Jordan.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 47-49, 52, 54, 55, 58-61, 64, 66, 67, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,336,435 to Kashyap et al [hereinafter Kashyap] in view of Jordan.

Kashyap discloses a medical device (8) having a medical item (1) placed therein, the device comprising:

a base and at least first (25) and second panels attached to the base;

a receptacle defined between the panels for the medical item therein, wherein the item has a particular temperature range for utilization; and

a temperature sensor assembly (30) to directly measure the temperature of the item;

wherein the device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the item and an external

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environment (oven 4) surrounding the medical device; the temperature sensor assembly includes a temperature sensor (31) disposed within the first panel to directly measure the temperature of the item; the receptacle is configured to enable the medical item to be in thermal relation with the sensor; the device is attached to a support structure/thermal treatment system (4); and the temperature sensor may be an IR temperature sensor; and the temperature sensor assembly is affixed to the first panel (25) (see figures 2, 4, and 6; column 3, lines 10-16; and column 4, lines 10-36).

Kashyap does not disclose the assembly comprising a display for visually indicating the measured temperature of the medical item.

Jordan discloses a medical device (10) for a medical item, the device comprising a housing defining a receptacle for receiving the medical item; and a temperature sensor assembly for directly measuring the temperature of the medical item, the assembly having a display for visually indicating the measured temperature of the medical item by using a temperature sensing strip (80) that provides a digital temperature measurement indicated by a digital temperature display. Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature as it is heated (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Referring to claims 47 and 59, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the assembly of Kashyap by providing a display for visually indicating the measured temperature of the medical item, as taught by Jordan, in order for the user to determine the actual temperature of the contents in the medical

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item before using the contents on a patient, and since Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature.

Furthermore, the method steps of claims 59-61, 64, 66, 67, and 70 will naturally be followed during the normal operation of the device disclosed above by Kashyap and Jordan.

6. Claims 57 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashyap and Jordan, as applied to claims 47-49, 52, 54, 55, 58-61, 64, 66, 67, 69, and 70 above, and further in view of U.S. Patent 4,585,441 to Archibald.

Kashyap and Jordan disclose a device and method having all of the limitations of claims 57 and 68; as stated above in paragraph 5, except for the device including a voice synthesizer to provide an audio indication of the temperature.

Archibald discloses a device for IV fluid control having a voice synthesizer to provide an audible alarming signal. Archibald teaches that using a voice synthesizer is beneficial since it allows a positive indication of the alarming source from other alarming sources that may be present simultaneously with the device (see column 4, lines 30-38)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Kashyap and Jordan by adding a voice synthesizer to state the temperature, as taught by Archibald, in order to audibly discern the temperature measurements of the item from other medical devices that may be present.

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7. Claims 47, 50-56, 59, and 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,994,021 to Smith et al [hereinafter Smith] in view of U.S. Patent 4,859,360 to Suzuki et al [hereinafter Suzuki].

Smith discloses a medical device comprising:

a base and at least first and second panels attached to the base;

a receptacle defined between the panels for receiving a medical item (bag) therein, wherein the item has a particular temperature range for utilization;

wherein the device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the item and an external environment surrounding the medical device; the first panel includes a handle (78/80) that can facilitate transporting and handling the device; and the device is attached to a support structure/thermal treatment system (e.g., a freezer) (see figure 3; column 2, line 44-53).

Smith does not disclose the device comprising a temperature sensor assembly to directly measure the temperature of the medical item and visually indicate the measured temperature of the medical item, wherein the temperature sensor assembly includes:

a plurality of temperature-sensitive substances each associated with a corresponding temperature range, each substance being responsive to a temperature of the item and providing a visual indication of the item temperature when the item temperature is within the corresponding temperature range; a temperature sensing strip providing a digital indication of the temperature; or a liquid crystal display to visually indicate the temperature.

Suzuki discloses a medical item (bag), the item comprising a temperature sensor assembly to directly measure the temperature of the medical item and visually indicate the

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measured temperature of the medical item. The temperature sensor assembly includes a plurality of temperature-sensitive substances each associated with a corresponding temperature range, wherein each substance is responsive to a temperature of the item and provides a visual indication of the item temperature when the item temperature is within the corresponding temperature range. The substances are formed on a strip that provides a digital, i.e., numerical, indication of the temperature. The temperature sensor assembly is a liquid crystal display for visually indicating the temperature of the item. Suzuki teaches that it is beneficial to provide a medical item with a visual temperature sensor assembly in order to easily determine if the medical item is at an acceptable temperature (see figures 1 and 3; column 4, line 67-column 5, line 18; column 17, lines 7-61; and column 18, lines 47-54).

Referring to claims 47 and 59, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Smith by providing a temperature sensor assembly for the medical item, as taught by Suzuki, in order for the user to easily determine the temperature of the item and determine if the medical item is at an acceptable temperature. Furthermore, referring to claims 59 and 62-67, the method steps of claims 59 and 62-67 will naturally be followed during the normal operation of the device disclosed above by Smith and Suzuki.

8. Claims 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,989,238 to Ginsburg in view of Jordan.

Ginsburg discloses a medical device (10) for a medical item (30), the device comprising: a base and at least first and second panels attached to the base;

a receptacle (28) defined between the panels for receiving the medical item (30), wherein the medical item has a particular temperature range for utilization;

a temperature sensor assembly (including a temperature sensor 34) to directly measure the temperature of the medical item; and

visual means (24) for displaying a set point temperature for the medical device;

wherein the temperature sensor assembly is affixed to one of the first panel, second panel, and base (e.g., the bottom panel of the housing 12) (see figures 1 and 2; column 2, lines 25-35 and 45-53; column 3, lines 2-7, 18-22, and 26-31; and column 4, line 48-column 5, line 17).

Ginsburg does not disclose the assembly comprising means for visually indicating the measured temperature of the medical item.

Jordan discloses a medical device (10) for a medical item, the device comprising a housing defining a receptacle for receiving the medical item; and a temperature sensor assembly for directly measuring the temperature of the medical item, the assembly having means for visually indicating the measured temperature of the medical item by using a temperature sensing strip (80) that provides a digital temperature measurement indicated by a digital temperature display. Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature (see figures 1, 3, and 4; column 6, lines 21-36 and 56-60; column 7, lines 15-17, 31-40, and 52-55; and column 8, lines 51-61).

Referring to claims 71 and 72, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Ginsburg by providing the temperature sensor assembly with means for visually indicating the measured temperature of the medical item, as taught by Jordan, in order for the user to determine the actual temperature of the

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contents in the medical item before using the contents on a patient, and since Jordan teaches that it is useful to provide the user with a visual indication of the actual medical item temperature.

Furthermore, the method steps of claim 72 will naturally be followed during the normal operation of the device disclosed above by Ginsburg and Jordan.

Response to Arguments

9. Applicant's arguments with respect to claims 47-72 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mirellys Jagan whose telephone number is 571-272-2247. The examiner can normally be reached on Monday-Friday from 11AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on 571-272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJ
May 5, 2005


GAIL VERBITSKY
PRIMARY EXAMINER